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10/537,027	01/05/2006	Koen Van den Heuvel	COCH-0148-US1	1143

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EXAMINER

WEST, JEFFREY R

ART UNIT	PAPER NUMBER
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2857

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Drawings

2. The drawing in Figure 1A is objected to because it does not have sufficiently descriptive labels. Blank boxes in drawings should be labeled descriptively unless it is a well-known component, specifically, blank boxes "104", "106", "108a", "108b", "108c", "110", "112" and "116", should be labeled descriptively.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "2", "4", "6", "9" (page 18, lines 21-30, page 19, line 4 to page 20, line 1, and page 22, line 13), "120" (page 20, line 20 and page 21, line 7).
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5)

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because they include the following reference character(s) not mentioned in the description: Steps 1.1-1.4, 2.1-2.2, 3.1-3.3, 4.1, and 5.1-5.4 in Figure 6).

5. The drawings are objected to because of the following informalities:

In Figure 1A an arrow is present pointing to the "mouse" but no corresponding reference character is provided.

The photographs/screenshots in Figures 4, 5, 8, 11, and 14-16 contain text/images that are indiscernible.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities:

On page 20, line 35, reference is made to "components 104-112" while components "105, 107", "109", and "111" are not illustrated

On page 21, line 5, reference is made to "input devices 108b" while Figure 1A illustrates "108b" as an interface.

Appropriate correction is required.

Claim Objections

8. Claims 1, 4, 5, 9, 13, 35, and 62 are objected to because of the following informalities:

In claim 1, line 2, to avoid problems of antecedent basis, "the recipient" should be ---a recipient---.

In claim 1, line 2, to avoid problems of antecedent basis, "prosthesis" should be -- -hearing prosthesis---.

In claim 1, line 5, to avoid problems of antecedent basis, "said instructions" should be ---said software instructions---.

In claim 1, line 7, to avoid problems of antecedent basis, "prosthesis" should be -- -hearing prosthesis---.

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In claim 1, line 8, to avoid problems of antecedent basis, "prosthesis" should be --
-hearing prosthesis---.

In claim 1, line 9, to avoid problems of antecedent basis, "the tests" should be ---
the one or more tests---.

In claim 1, line 9, to avoid problems of antecedent basis, "prosthesis" should be --
-hearing prosthesis---.

In claim 4, line 2, to avoid problems of antecedent basis, "the tests" should be ---
the one or more tests---.

In claim 5, line 2, to avoid problems of antecedent basis, "the tests" should be ---
the one or more tests---.

In claim 8, line 2, to avoid problems of antecedent basis, "the tests" should be ---
the one or more tests---.

In claim 9, line 1, to avoid problems of antecedent basis, "prosthesis" should be --
-hearing prosthesis---.

In claim 13, line 2, to avoid problems of antecedent basis, "the test" should be ---
the one or more tests---.

In claim 35, line 3, to avoid problems of antecedent basis, "said instructions"
should be ---said software instructions---.

In claim 35, line 4, to avoid problems of antecedent basis, "prosthesis" should be
---hearing prosthesis---.

In claim 35, line 5, to avoid problems of antecedent basis, "the recipient" should
be ---a recipient---.

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In claim 35, line 5, to avoid problems of antecedent basis, "prosthesis" should be ---hearing prosthesis---.

In claim 35, line 6, to avoid problems of antecedent basis, "the tests" should be -- -tests---.

In claim 35, line 6, to avoid problems of antecedent basis, "prosthesis" should be ---hearing prosthesis---.

In claim 62, lines 2-3, to avoid problems of antecedent basis, "the recipient" should be ---a recipient---.

In claim 62, line 4, to avoid problems of antecedent basis, "prosthesis" should be ---hearing prosthesis---.

In claim 62, line 4, to avoid problems of antecedent basis, "a test" should be ---one or more tests---.

In claim 62, line 5, to avoid problems of antecedent basis, "prosthesis" should be ---hearing prosthesis---.

In claim 62, line 6, to avoid problems of antecedent basis, "prosthesis" should be ---hearing prosthesis---.

In claim 62, line 7, to avoid problems of antecedent basis, "the tests" should be -- -the one or more tests---.

In claim 62, line 7, to avoid problems of antecedent basis, "prosthesis" should be ---hearing prosthesis---.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 10 and 11 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10 and 11 attempt to further limit parent claim 9 “wherein the storage means is a portable storage means, to be physically forwarded to the clinician of the recipient” and “wherein the portable storage means is a magnetic disc”, respectively. Claim 9, however, indicates that the “storage means is in the prosthesis”. Turning to the specification:

In alternate embodiments of the invention, the computer may be at a location remote from a clinician of the recipient, such as the recipient's home. In such embodiments, the computer is preferably operable to store results of the tests on a storage means for forwarding to the clinician of the recipient. The storage means may be in the prosthesis. Alternatively, the storage means may be a portable storage means such as a magnetic disc, to be physically forwarded to the clinician of the recipient. (page 5, lines 3-8)

In another embodiment, the computer can be at a location remote from the recipient's clinician. In a preferred such embodiment, the computer is housed in the recipient's home or at a location that is relatively more convenient for the recipient to access than the clinic. In such embodiments, the results of the tests can be stored in a storage means in the hearing prosthesis or can be stored in a suitable storage means used in conjunction with the computer. For example, the results can be saved on a portable storage means, such as a disc, and then provided to a clinician responsible for managing the after-care of the recipient of

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the prosthesis. The stored results may be retained by the recipient and only provided to the clinician on the recipient's next visit to the clinician or can be posted to the clinician using normal mail services. (page 8, line 30 to page 9, line 3)

The computer 102 itself comprises a central processing unit(s) (simply referred to as a processor hereinafter) 104, a memory 106 which may include random access memory (RAM) and read-only memory (ROM), input/output (IO) interfaces 108a, 108b & 108c, a video interface 110, and one or more storage devices generally represented by a block 112 in FIG. 1a. The storage device(s) 112 can comprise one or more of the following: a floppy disc, a hard disc drive, a magneto-optical disc drive, CD-ROM, magnetic tape or any other of a number of non-volatile storage devices well known to those skilled in the art. Each of the components 104 to 112 is typically connected to one or more of the other devices via a bus 114 that in turn can consist of data, address, and control buses. (page 20, line 28 to page 21, line 2)

The system 100 is simply provided for illustrative purposes and other configurations can be employed without departing from the scope and spirit of the invention. Exemplary computers on which the embodiment can be practiced include IBM-PC/ATs or compatibles, one of the Macintosh™ family of PCs, Sun Sparcstation™, or the like. The foregoing are merely exemplary of the types of computers with which the embodiments of the invention may be practiced. Typically, the processes of the embodiments, described hereinafter, are resident as software or a program recorded on a hard disk drive (generally depicted as block 112 in FIG. 1a) as the computer readable medium, and read and controlled using the processor 104. Intermediate storage of the program and pixel data and any data fetched from the network may be accomplished using the semiconductor memory 106, possibly in concert with the hard disk drive 112.

In some instances, the program may be supplied to the user encoded on a CD-ROM or a floppy disk (both generally depicted by block 112), or alternatively could be read by the user from the network via a modem device connected to the computer, for example. Still further, the software can also be loaded into the computer system 100 from other computer readable medium including magnetic tape, a ROM or integrated circuit, a magneto-optical disk, a radio or infra-red transmission channel between the computer and another device, a computer readable card such as a PCMCIA card, and the Internet and Intranets including email transmissions and information recorded on websites and the like. The foregoing are merely exemplary of relevant computer readable mediums. Other computer readable mediums may be practiced without departing from the scope and spirit of the invention. (page 21, lines 8-30)

As can be seen in the cited sections above, the instant disclosure does describe a storage means as a portable storage means comprising a magnetic disc. The instant disclosure, however, describes this implementation as an embodiment distinct from providing a storage means in the prosthesis. Therefore, the specification does not sufficiently enable one having ordinary skill in the art to make/use the invention as claimed, specifically, with "a portable storage means" including "a magnetic disc" that is "in the prosthesis".

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claim 62 is considered to be non-statutory. Claim 62 presents a computer program comprising software code. This software code is considered to be a data structure that does not define any functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. It has been held that such a data structure is considered to be non-statutory under 35 U.S.C. 101 (See e.g., *Warmerdam* 33 F.3d at 1361. 31 USPQ2d at 1760).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1, 2, 35, and 62, as may best be understood, are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,334,072 to Leysieffer.

With respect to claim 1, Leysieffer discloses a system for performing one or more tests on a hearing prosthesis (column 8, lines 24-26), the system being usable at least in part by the recipient of the prosthesis (column 6, lines 53-64), the system comprising: a computer (column 6, lines 49-52) that processes software instructions and outputs signals in response to said instructions (column 7, lines 38-52); a prosthesis interface means that provides transfer of signals from said computer to the prosthesis and/or from the prosthesis to the computer (column 6, lines 45-64); and an interface that allows the recipient of the prosthesis to at least partially control at least some aspect of the tests performed on the prosthesis that is interfaced with the computer (column 6, line 65 to column 7, line 7).

With respect to claim 2, Leysieffer discloses that the computer is a stand alone computer adapted to perform one or more tests on the hearing prosthesis (column 6, lines 49-52).

With respect to claim 35, Leysieffer discloses a method of testing a hearing prosthesis (column 8, lines 24-26), the method comprising: providing a first computer (column 6, lines 49-52) that processes software instructions and outputs signals in response to said instructions (column 7, lines 38-52); transferring the signals from the first computer to the prosthesis (column 6, lines 45-64); and providing an

interface that allows the recipient of the prosthesis to at least partially control at least some aspect of the tests performed on the prosthesis that is interfaced with tile first computer (column 6, line 65 to column 7, line 7).

With respect to claim 62, Leysieffer discloses a computer program (column 7, lines 38-52) configured to make a computer perform one or more tests on a hearing prosthesis (column 8, lines 24-26), the computer program being operable at least in part by the recipient of the hearing prosthesis (column 6, lines 53-64), the computer program comprising: code for generating instructions to the prosthesis in carrying out a test (column 7, lines 38-52 and column 8, lines 24-26); code for transferring the instructions to the prosthesis (column 6, lines 45-64); code for implementing an interface that allows the recipient of the prosthesis to at least partially control at least some aspect of the tests performed on the prosthesis (column 6, line 65 to column 7, line 7).

Leysieffer discloses that the computer is operable to store results of the tests for later assessment (column 3, lines 53-58).

Leysieffer discloses that the computer is operable to store results of the tests on a storage means (column 3, lines 53-58).

Leysieffer discloses that the storage means is in the prosthesis (column 6, lines 39-45).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

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obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer in view of U.S. Patent No. 5,626,629 to Faltys et al.

As noted above, the invention of Leysieffer teaches many of the features of the claimed invention and while the invention of Leysieffer does teach a computer that process software instructions and output signals to perform testing of a hearing prosthesis (column 7, lines 38-52) as well as allowing real-time (i.e. immediate) visualization of results or storing data for later analysis (column 3, lines 53-58), Leysieffer does not explicitly indicate that the computer is located at a clinic for use by the recipient when visiting the clinic.

Faltys teaches programming of a speech processor for an implantable cochlear stimulator with a personal computer (column 5, lines 20-26) located at a clinic for use by the recipient when visiting the clinic (column 4, lines 26-33 and column 13, lines 61-64) for immediate presentation of results to a clinician (column 7, lines 42-65).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer to explicitly indicate that the computer is located at a clinic for use by the recipient when visiting the clinic, as taught by Faltys, because, as suggested by Faltys, the combination would have improved the system of Leysieffer by providing the apparatus at a location with experts and specialists, such as

audiologists, that have the experience and knowledge to properly adjust the hearing system of Leysieffer, thereby ensuring the maximum amount of functionality of the system (column 7, line 42 to column 8, line 13).

17. Claims 6, 7, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer in view of U.S. Patent No. 5,909,497 to Alexandrescu.

As noted above, the invention of Leysieffer teaches many of the features of the claimed invention and while the invention of Leysieffer does teach a computer that process software instructions and output signals to perform testing of a hearing prosthesis (column 7, lines 38-52) as well as allowing real-time (i.e. immediate) visualization of results or storing data for later analysis (column 3, lines 53-58), Leysieffer does not explicitly indicate that the computer is located remote from a clinician at a recipient's home with the ability to transmit data to a clinician.

Alexandrescu teaches a programmable hearing aid instrument and programming method thereof including a computer interface (column 4, lines 4-19) located at a location remote from a clinician of the recipient at the recipient's home (column 8, lines 19-33) wherein the computer interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49) as well as deliver data specific to the hearing prosthesis electronically to a computer of a clinician/specialist of the recipient (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer to explicitly indicate that the computer is located remote from a clinician at a recipient's home with the ability to transmit data to a clinician, as taught by Alexandrescu, because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

18. Claims 8-11, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer in view of Alexandrescu and further in view of U.S. Patent No. 5,626,629 to Faltys et al.

As noted above, the invention of Leysieffer and Alexandrescu teaches many of the features of the claimed invention and while the invention of Leysieffer Alexandrescu does teach a computer that process software instructions and output signals to perform testing of a hearing prosthesis (Leysieffer; column 7, lines 38-52) as well as allowing real-time (i.e. immediate) visualization of results or storing data for later analysis (Leysieffer; column 3, lines 53-58), Leysieffer does not explicitly indicate that the storage for later analysis is a portable magnetic disk for use by a clinician.

Faltys teaches programming of a speech processor for an implantable cochlear stimulator with a personal computer (column 5, lines 20-26) located at a clinic for use by the recipient when visiting the clinic (column 4, lines 26-33 and column 13, lines 61-64) based on patient specific data (column 11, lines 34-39 and column 12, lines 13-39) stored in a portable magnetic disk (column 22, lines 35-44)

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer and Alexandrescu to explicitly indicate that the storage for later analysis is a portable magnetic disk for use by a clinician, as taught by Faltys, because, as suggested by Faltys and known by one having ordinary skill in the art, magnetic disks are common methods for transporting data and therefore the combination would have provided increased efficiency of the system of Leysieffer and Alexandrescu by allowing the user to transport specific patient data (column 11, lines 34-39, column 12, lines 13-39, and column 22, lines 35-44) while improving the apparatus of Leysieffer and Alexandrescu by providing the data to specialists, such as audiologists, that have the experience and knowledge to properly adjust the hearing system of Leysieffer and Alexandrescu, thereby ensuring the maximum amount of functionality of the system (column 7, line 42 to column 8, line 13).

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

U.S. Patent No. 6,879,693 to Miller et al. teaches a method and system for external assessment of hearing aids that include implanted actuators.

U.S. Patent Application Publication No. 2002/0176584 to Kates teaches an apparatus and methods for hearing aid performance measurement, fitting, and initialization.

U.S. Patent No. 6,366,863 to Bye et al. teaches a portable hearing-related analysis system.

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus and method of programming a digital hearing aid.

U.S. Patent No. 4,847,617 to Silvian teaches a high speed digital telemetry system for implantable devices.

U.S. Patent No. 5,609,616 to Schulman et al. teaches a physician's testing system and method for testing an implantable cochlear stimulator.

EP Patent Application Publication No. 0 124 930 to Crosby et al. teaches a cochlear implant system for an auditory prosthesis.

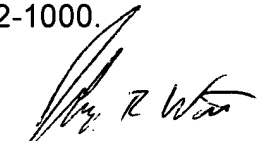
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (571)272-2226. The examiner can normally be reached on Monday through Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (571)272-2216. The fax phone number

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for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jeffrey R. West
Examiner – AU 2857

February 19, 2007